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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/658,551	09/08/2000	Craig Robert Jeffrey	1171/38910/79	3896

7590 12/10/2003

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EXAMINER

PATEL, MITAL B

ART UNIT	PAPER NUMBER
3743	7

DATE MAILED: 12/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/658,551	JEFFREY ET AL.
	Examiner Mital B. Patel	Art Unit 3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 September 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4 and 11-13 is/are rejected.
- 7) Claim(s) 5-10 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> .	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Response to Amendment/Arguments

1. Applicant's arguments filed 9/30/03 have been fully considered but they are not persuasive.
2. In response to Applicant's remarks regarding the Abstract, it should be noted that Applicant's Abstract makes reference to the term "disclosed" which should be avoided since it is an implied phrase as mentioned below under the specification objection.
3. In response to Applicant's remarks concerning the Information Disclosure Statement, it should be noted that the Examiner did consider the IDS and it was attached to the Office Action mailed 8/13/03. However, the Examiner has attached a copy of the signed IDS to this action for the Applicant's reference.
4. In response to Applicant's remarks that the claims have been amended to positively recite the body of liquid, it should be noted that the claim recites "a container which **in use** includes a body of liquid, having a substantially constant level **in use**." The term "in use" does not constitute a positive recitation.
5. In response to applicant's argument that Brawn does not teach a body of liquid having a substantially constant level, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative

difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Specification

6. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Objections

7. Claims 5-7 are objected to because of the following informalities: In regard to claim 5, it appears that the Applicant amended "overflow means" to "overflow outlet." Furthermore, it appears that Applicant has attempted to further define the overflow outlet by its position but it's unclear if the outlet is adjacent the constant level. In regard to claims 6 and 7, Applicant amended "damping means" to damping. However, the term "damping" imparts no structure, and therefore, the Examiner suggests that the Applicant amend the claim to read "damping means." Appropriate correction is required.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Brawn (US 3,972,326).

10. **As to claim 1**, Brawn teaches a pressure regulating device for use with a breathing assistance apparatus which conveys inhalatory gas to, and removes exhalatory gas from a patient requiring breathing assistance comprising a container 1, 20 which includes a body of liquid 9,24, having a substantially constant level in use, terminal conduit 4,33 including proximate and distal ends, the proximate end adapted for connection to a breathing assistance apparatus and in use accepting exhalatory gas therefrom, and the distal end submerged in the body of liquid, such that in use the mean pressure of the gas supplied to a patient is adjusted by the level to which the distal end is submerged in the body of water.

11. **As to claim 2**, Brawn teaches a device further comprising a connector attached to the container and engaging the terminal conduit, whereby in use the terminal conduit may be adjusted in axial position in predetermined increments, with respect to the connector.

12. **As to claim 13**, Brawn teaches a pressure regulating device for use with a breathing assistance apparatus which conveys inhalatory gas to, and removes

exhalatory gas from a patient requiring breathing assistance comprising a container **1**, **20** which includes a body of liquid **9,24** having a substantially constant level in use, and a terminal conduit **4,33** including proximate and distal ends, the proximate end adapted for connection to a breathing assistance apparatus and in use accepting exhalatory gas therefrom, and the distal end submerged in the body of liquid, such that in use the resultant bubbling occurring in the body of liquid produces relatively small controlled perturbations in the pressure of the gas supplied to the patient.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 11 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Faithfull et al (US 6,041,777).

14. As to claim 11, Faithfull teaches a breathing assistance apparatus for supplying gas to a patient to assist the patient's breathing including a gas supply **318** adapted to supply gas to the patient, an interface **304** including a plurality of ports (the Examiner considers the ports to be that defined by Y-connector) adapted to deliver the gas to the patient, an inhalatory conduit (the part of the Y-connector that houses the valve **310**) for conveying the gas from the gas supply to the interface, exhalatory conduit (the part of the Y-connector that houses the valve **308**) for conveying the patient exhalations from the interface, a container **326** which in use includes a body of liquid, a terminal conduit **314** including proximate and distal ends, the proximate end adapted for connection to

the exhalatory conduit and in use accepting exhalatory gases therefrom, the distal end submerged in the body of liquid, such that in use the patient is delivered a substantially constant mean pressure, the mean pressure adjusted by the level to which the distal end is submerged in the body of water.

15. **As to claim 12**, Faithfull teaches a breathing assistance apparatus further comprising humidification means (**See Col. 16, lines 29-30**) for humidifying gases prior to delivery to the patient, disposed within or in fluid communication with the inhalatory gases transport means.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brawn (US 3,972,326).

18. **As to claim 3**, Brawn teaches essentially all of the limitations except for wherein the terminal conduit includes at least one partial groove and the connector includes at least one matching partial resilient ridge or toggle. It should be noted that Brawn does teach that a friction fit connection rather than the type recited. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to make the terminal conduit means includes at least one partial

groove and the connection means includes at least one matching partial resilient ridge or toggle because Applicant has not disclosed how the particular limitation solves a stated problem, is advantages over the prior art, or provides an unexpected result. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the friction fit since the connection between the two elements is still maintained.

19. **As to claim 4,** Brawn teaches essentially all of the limitations except for wherein the predetermined increments are one half centimeters each. Applicant has not disclosed how the particular limitation solves a stated problem, is advantages over the prior art, or provides an unexpected result. Furthermore, the particulars of the limitation are directed to the method of using the device and therefore, little or no patentable weight is given to the limitation. Additionally, it would have been obvious to one of ordinary skill in the art to make such predetermined increments depending on the intended therapy and patient.

Allowable Subject Matter

20. Claims 5-10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5988164, US 4829998, US 5195515, US 4597917, US 4232667, US 4010748, US 3990441, US 3923057, and US 3912795.
22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 703-306-5444. The examiner can normally be reached on Monday-Friday (8:00 - 4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.


Aaron J. Lewis
Primary Examiner

mbp